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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/553,969	04/21/2000	Donald G. Wallace	17067-002040	6560

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EXAMINER	
CHANNAVAJJALA, LAKSHMI SARADA	
ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/553,969	WALLACE ET AL.	
	Examiner	Art Unit	
	Lakshmi S. Channavajjala	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 December 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,19,21,24-27,30-32 and 34-63* is/are pending in the application.

4a) Of the above claim(s) *37-63* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,19,21,24-27,30-32 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/13/10;12-9-10;1/21/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of amendment and response dated 12-1-10 and IDS dated 12-9-10 and 1-21-11 is acknowledged.

New claims 37-63 are pending. Claims 1, 19, 21, 24-27, 30-32 and 34-63 are pending in the instant application.

Applicants submit that the instant application is a continuation of USSN 09/032,370 filed February 27, 1998. At the time the presently claimed invention was made, it was owned or subject to an obligation of assignment to Fusion Medical Technologies, Inc. The Reich Patent was filed on February 6, 1997 and published on August 3, 1999. Reich was, at the time the presently claimed invention was made, owned by or subject to an obligation of assignment to Fusion Medical Technologies, Inc. In light of the evidence that the Reich patent cannot be employed as prior art under 35 USC 102(a), (b) or (e), the rejections of record have been withdrawn and the following new rejection is applied to the pending claims:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims **1, 19, 21, 24-25, 29, 31, 34 and 36 are** rejected under 35 U.S.C. 103(a) as being unpatentable over **US 4,482,386 to Wittwer et al (Wittwer) and US 5135755 to Czech et al, and further in view of any one of JP 05308969 (JP 969, abstract only) or JP Laid-open publication No. 6-254148 discussed in the English**

translation of the Official Japanese Action in JP Patent Application No. 2001-502866 (English translation submitted on PTO-1449 by applicants on 1-28-10).

Wittwer et al teach conditioned water-swellable hydrocolloids for use in mechanical forming processes such as die molding or injection molding in preparing shaped articles (abstract, col. 10 and col. 2, L 66 through col. 3, l 13). Wittwer teaches a number of polymers such as protein or non-biological polymers for preparing swellable hydrocolloids including gelatin (col. 2, L 37-57). Example in col. 4 describes the preparation of gelating preparation, where in gelatin is conditioned or hydrated to 15% water content and the gelating granules. Further, Wittwer teaches that gelatin is in a granulated form with a mean particle diameter of 0.2 to 4 mm. (claim 6). With respect to the degradation claimed, the property of degradation is associated with gelatin. Wittwer does not teach the hydrocolloid in an applicator but suggests that the granulated gelatin is coupled with a molding unit such as an injection molding machine and therefore the claimed hydrogel being in an applicator with an extrusion orifice so as to be able to inject gelatin hydrocolloid would have been within the scope of a skilled artisan. Even though Wittwer fails to exemplify other swellable polymers, it would have been obvious for a skilled artisan to choose a biological polymer such as protein or a non-biological polymer or a synthetic polymer to prepare swellable hydrocolloids because Wittwer suggests that the process of preparing a swellable hydrocolloids of predetermined water content, that are suitable for preparing moldable or shaped articles can also be prepared with synthetic polymers.

Wittwer does not teach a combination of cross-linked gelatin and non-crosslinked gelatin, required by the instant independent claim 1 or the combination of crosslinked gelatin and a non-crosslinked polymeric material of claim 34. Wittwer also fails to teach a combination of crosslinked gelatin and a non-biological polymer (for instant claims 31-32 and 36).

JP 969 teaches preparation of gelatin carriers for immobilized enzymes in which an enzyme is present in the reinforced gelatin gel and the gel is further covered with a crosslinked gelatin gel. JP 969 states that the preparation thus made protects the enzyme activities in the non-crosslinked gel by crosslinking the shell.

JP publication No. 6-254148 (according to the description given the translation) teaches the combination of crosslinked and non-crosslinked gelatin for hemostatic application.

Czech teaches crosslinked hydrogels and their use for wound dressing. Czech states that the prior art teachings of hydrogel/colloid systems, involving combinations of polymers such as biological and non-biological polymers like gelatin, collagen and their combinations with synthetic polymers exhibit a number of disadvantages such as lack of mechanical strength after absorbing wound secretions, not transparent and hence does not allow visual inspection of the wound (col. 1, 10-49). Therefore Czech suggests crosslinking hydrogels based on a combination of synthetic and biopolymers, whereby the two polymers are cross linked. The composition of Czech contains a biopolymer, a multivalent alcohol, one uncrosslinked synthetic polymer and suggests gelatin for natural polymer (col. 2)

Thus, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to include not only cross-linked gelatin but also non-crosslinked gelatin in the conditioned gelatin hydrocolloid composition of Wittwer and further include an uncrosslinked polymer such as gelatin (JP references) or an uncross linked synthetic polymer (Czech) in the composition of Wittwer containing gelatin hydrocolloid and employ the composition not only for molding into shaped articles but also as a wound dressing hydrogel because Czech teaches the advantages of having crosslinked as well as non crosslinked polymers in that the wound dressing hydrogels improve the mechanical strength, stability and transparency so as to observe the wound during healing process. A skilled artisan would have expected increased strength and elasticity of the hydrogel containing a cross and non-crosslinked polymer, rapid absorption of wound secretion over a long period of time.

JP 969 suggests protecting the substances such as enzymes present in the gelatin gel by crosslinking the top gelatin shell and JP publication No. 6-254148 notes that it is common to use both types in hemostatic applications. While the references do not recite the ratio of the cross-linked to the non-crosslinked gelatin or other polymer, a skilled artisan would have determined the amounts of the same based on the amount of cross-linking desired such that the desired mechanical strength of the film is achieved. For the claim limitation that cross-linked gelatin provides voids in which the non-crosslinked gelatin is present, a skilled artisan would expect that the combination of crosslinked gelatin and non-crosslinked polymer results in the claimed arrangement.

. Further, while Wittwer does not teach a combination of gelatin and a non-biological polymer, Wittwer teach both biological and non-biological polymers and Czech also teaches a combination of biopolymers and synthetic polymers. Therefore, a skilled artisan would have employed a combination of gelatin and other non-biological polymers such as polyacrylates and still expect to achieve resorbable composition that can be employed for wound healing.

Claims 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,482,386 to Wittwer et al (Wittwer) and US 5135755 to Czech et al, and any one of JP 05308969 (JP 969, abstract only) or JP Laid-open publication No. 6-254148 discussed in the English translation of the Official Japanese Action in JP Patent Application No. 2001-502866 (English translation submitted on PTO-1449 by applicants on 1-28-10), as applied to claims 1, 19, 21, 24-25, 29 and 34 above, and further in view of US 5643596 to Pruss et al and/or US 4,515,637 to Cioca.

Wittwer teaches gelatin or synthetic polymers that are swellable and also suitable for injection molding to prepare shaped articles. Wittwer teaches natural and synthetic polymers are suitable for the preparation of injectable hydrocolloids, but fails to teach an active agent (claim 25) such as a clotting agent (claim 26) or thrombin. Czech teaches gelatin hydrocolloid gels for use in wound healing.

Cioca teaches thrombin as an effective clotting factor for stoppage of bleeding locally (col. 2).

Pruss teaches a hemostatic patch comprising clot promoting amounts of thrombin, aminocaproic acid (EACA) present on the substrate of absorbable gelatin sponge. Pruss teaches that EACA acts like fibrinogen and is converted to fibrin in the presence of thrombin and thus provide blood clot formation (abstract and col.2).

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to use swellable hydrocolloids of Wittwer containing gelatin polymer and non-crosslinked gelatin (JP references or Czech) for delivering active agents such as coagulating factors to the desired site because Pruss suggests gelatin patches for delivering therapeutic agents such as coagulating agents. Further, Pruss and Cioca teach thrombin for clot formation. A skilled artisan would have expected thrombin to function as a coagulation factor in the hydrogel composition of Wittwer with an expectation of achieving the desired clotting or coagulation.

Claims 30 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,482,386 to Wittwer et al (Wittwer) and US 5135755 to Czech et al, and any one of JP 05308969 (JP 969, abstract only) or JP Laid-open publication No. 6-254148 discussed in the English translation of the Official Japanese Action in JP Patent Application No. 2001-502866 (English translation submitted on PTO-1449 by applicants on 1-28-10), as applied to claims 1, 19, 21, 24-25, 29 and 34 above, and further in view of US 4,124,705 to Rothman et al or Rothman and US 6,129,761 to Hubbell .

Wittwer and Czech fail to teach the combination of a cross-linked protein and a non-biological polysaccharide

Rothman et al (hereafter Rothman) discloses an agent for intravascular administration consisting of a suspension of minute particles of a polysaccharide that blocks the finer blood vessels (abstract, lines bridging col. 1-2 and paragraph bridging col. 11-col. 12). The polysaccharide of Rothman is biodegradable and resorbable because Rothman describes that the hydrophilic swellable particles are broken down by alpha-amylase in the blood plasma (col. 2, l 4-16) and further, according to the instant claim 35, the ability to be resorbable is inherent to the polysaccharide of Rothman. Similarly, the ability to swell is a property inherent to the polysaccharides described by Rothman. Rothman teaches a size range of 0.1 to 300 microns (col. 5, L 18-36), which overlaps with the claimed range of 0.01 mm to 5 mm (10 microns-5000 microns). Rothman further describes that the polymeric gel particles are produced by disintegrating the larger pieces of gel, which reads on fragmented gel claimed in the instant (col. 8, L 3-14). With respect to the limitations of "single phase" and "substantially free form a free aqueous phase", Rothman does not teach including any other substance or component in the polysaccharide suspension other than for the formation of the gel or the ability to form a gel, and also states that the gels contain more than 50% by weight water but less than 98%water (col. 4, L 58-70), which implies that the gels do not contain any free water. Rothman discloses that the particulate suspension is injected intravascularly (col. 8, L 31-48), in conjunction with a therapeutic (col. 9, L 25-34) or a diagnostic agent (col. 8, L 49 through col. 9, L 24). Further the

particulate suspension containing polysaccharide particles (of Rothman) is a single phase aqueous polysaccharide. Rothman teaches inclusion of therapeutic agents such as coagulation factors (col. 9, L 25-35).

Hubbell teaches injectable hydrogel compositions useful for delivering cells or other bioactive agents via injection and thus provide engraftment and a 3-D template for new cell growth, custom molding of implants as well as implantation of tissues (abstract and col. 5, L 5-23) . The polymers of Hubbell include biodegradable, biocompatible hydrogels such as polylactides, polyanhydrides, polysaccharides and natural polymers such as gelatin, collagen, fibrin etc (col. 7-8), all of which described in the instant. Hubbell also teaches combination or mixtures of polymers (col. 8, L 63 –col. 9, L 12). It would have been obvious for one of an ordinary skill in the art at the time of the instant invention was made to combine other synthetic and natural swellable polymers of Rothman or Hubbell with the polysaccharide swellable polymers of Wittwer for administration because Wittwer suggests that protein as well synthetic polymers are suitable for preparing injection moldable articles, Rothman suggests polysaccharides and Hubbell suggests several swellable hydrogel polymers (both natural polymers such as gelatin and synthetic polymers) as well as their combinations for administering active agents to the localized or for tissue remodeling or preparing shaped moldable articles. Accordingly, a skilled artisan would have expected to be able to administer active agents or promote tissue engraftment with individual as well as mixtures of hydrogel polymers.

Newly submitted claims 37-63 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The newly presented claims now require a device consisting of a syringe and cross-linked gelatin biodegradable gel (claim 37); further with a bioactive agent (claim 40), a composition of matter comprising the device of claim 37 and a sterile package, a kit comprising the device of claims 45 or 51 and a method of providing the gel and delivering the gel. The newly presented claims do not require that the gelatin gel or any non-crosslinked protein be combined with a non-cross linked gelatin or any other polymeric material (such as that claimed in the instant claim 1, 34-36). The new claims also do not require that cross linked gelatin or crosslinked polymer is present in the voids of a non-crosslinked gelatin (or polymer) and hence has different structural and chemical requirements. Pending claims do not require the limitations of the kit or that the limitations of the new method. Hence the newly elected claims are independent and distinct from the originally elected claims.

Examiner notes that claim 49-50 claim the same subject matter and hence duplicate.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 37-63 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Response to Arguments

Applicant's have not argued the teachings of the prior art of record with respect to examined claims, except providing the common ownership statement under 35 USC 103(a) to over come the reference of Reich. However, the previously examined claims have been rejected over new combination of references. While applicants argued the prior art in light of the newly added claims, the new claims have been considered non-elected in light of the above explanation I the preceding paragraphs.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -5.30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila G. Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lakshmi S Channavajjala/
Primary Examiner, Art Unit 1611
February 14, 2011